

REMARKS

Favorable consideration of the subject application is respectfully requested in view of the above amendments and following remarks. This Amendment and Reply is responsive to the final Office action mailed February 24, 2009 and is being filed with a Petition for an Extension of Time of one month, extending the time for response to June 24, 2009. This Amendment and Reply accompanies Applicants' Request for Continued Examination (RCE).

Claim 1 has been canceled and claims 2, 4, 5, 6, 9, 10, 16, 19, 24, 29, 32, 58, 60 and 65 have been amended. Claim 1 has been canceled without acquiescing in the outstanding rejection and without prejudice to applicants' ability to present the same or a similar claim in a related patent application. Claims 2, 5, 6, 9, 10, 16, 19, 24, 32, 58, 60 and 65 have been amended to delete reference to (now canceled) claim 1, and claim 29 has been amended to delete reference to (now canceled) claim 1 and depend from currently pending independent claims 6, 18 and 56.

Claim 6 has been amended to specify an interventional catheter assembly comprising, *inter alia*, a torque selection feature providing operator selection of preselected torque levels delivered by the drive assembly to the drive shaft and the operating head independent of the rotational speed. This feature of applicants' claimed interventional catheter assembly is described in the application, as filed and as published, for example, at paragraph 0042.

Claim 18 has been amended to specify an interventional catheter assembly comprising, *inter alia*, actuator *slidably* mounted on the catheter system distally to the control pod and in operable communication with the drive system, the actuator incorporating a switch that activates at least one of the drive system and an aspiration system. These features are described in the application, as filed and as published, for example, at paragraph 0064.

Claim 56 has been amended to more clearly and definitely recite certain features of an interventional catheter incorporating a guidewire brake control system in which a guidewire brake is operable to clamp a guidewire when engaged and allow translation of the guidewire through the brake when released; a guidewire brake interrupt that prevents the drive system from being actuated when the guidewire brake is in a release position; and a selectable interrupt override control that, when actuated, provides a guidewire brake operating mode that permits an operator to translate and/or rotate the drive shaft and the operating head at low speed while the

guidewire is simultaneously moved. These features are described in the application, as filed and as published, for example, at paragraph 0063.

Claims 2-7, 9, 10, 16-19, 24, 27-29, 32, 56 and 58-65 are pending in the application, with claims 6, 18 and 56 being in independent format. It is submitted that the above amendments are fully supported by the specification as it was originally filed and that none of the amendments constitutes new matter.

Claim Rejections – 35 USC § 103

Claim 1 was rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (U.S. Patent 6,398,755) in view of Wulfman et al. U.S. Patent Publication US 2002/0007190 or Clement et al. U.S. Patent 6,565,588. Claim 1 has been canceled, without acquiescing in the outstanding rejection and without prejudice to applicants' ability to present the same or a similar claim in a related patent application. Cancellation of claim 1 moots this rejection.

Claims 6 and 7 were rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (U.S. Patent 6,398,755) in view of Grinberg et al. (U.S. Patent 5,921,956). This rejection is respectfully traversed in view of the above amendment and the following remarks.

Belef et al. disclose a catheter and catheter drive unit providing controlled translation of a rotatable catheter core with an operative element, e.g. an atherectomy cutter, at its distal end. The Examiner notes that Belef et al. fail to teach a torque selection feature and relies on Grinberg et al. for the teaching of a torque selection feature. Grinberg et al. disclose a common driver, e.g. a motorized handpiece that may be used with a plurality of surgical instruments, each instrument having different rotational and torsional limits. The handpiece is manipulated by the surgeon to steer a distal tip of the instrument in surgical operations such as knee surgeries (*See*, e.g., Col. 7, lines 39-41).

To prevent an operator from inadvertently operating any of the surgical instruments outside its rotational and torsional limits, each instrument is encoded to provide a signal to the handpiece that, when the instrument is mounted on the handpiece, communicates the rotational and torsional limits for that particular instrument to the control unit. The control unit thus controls the speed of and torsion applied by the motor depending on and based on information provided by the instrument mounted in the handpiece, so that the speed and torsion applied by

the motor doesn't exceed safe limits for that particular instrument. (See, Col. 7, lines 49-62.)

This rotational and torsional control is not and cannot be exerted by an operator, except through the choice of a particular instrument to be mounted on the handpiece.

Grinberg et al. reference a commonly assigned patent, U.S. Patent 4,705,038 with respect to speed and torque control techniques. The '038 patent discloses a single motor surgical system adapted to operate a set of different surgical devices having different operational limits. Each device has an indicator that denotes its operational limit. The sensor is adapted to limit the torque applied by the motor and limit the range of speed of the motor and is responsive to the indicator(s) to limit the voltage applied to the motor, while the motor is adapted to maintain its speed in accordance with the voltage applied. The sensor is responsive to limit the current applied to the motor to limit the torque delivered by the motor. (See, e.g., Col. 1, line 39 – Col. 2, line 1. Speed control is described in detail at Col. 5, starting at line 48; the torque limit setting is described in detail at Col. 6, starting at line 20.)

Pending claim 6 recites an interventional catheter assembly having, *inter alia*, a torque selection feature providing *operator selection of preselected torque levels* delivered by the drive assembly to the drive shaft and the operating head *independent of the rotational speed*. The selectable torque feature of applicants' system permits *an operator* to determine the torque delivered to the operating head separately from the rotational speed. This is useful, for example, when the interventional catheter is used to remove different types of lesions. Some lesions that are composed of hard material, for example, may require operation at a high torque setting, while other, softer lesions, may be removed using a lower torque setting, providing an additional level of safety.

The Examiner states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter assembly of Belef with the adjustable torque of Grinberg so that the surgeon has control over the catheter assembly. Applicants disagree that Grinberg et al. teach or suggest an adjustable torque feature that would render applicants' pending claims obvious. Applicants believe that the "adjustable" torque feature of Grinberg et al. can only be viewed as "adjustable" under two circumstances: (1) when an operator operates an instrument over a range of speeds (e.g. between about 100 rpm and 5000 rpm, *See*, Col. 7, lines 52-55), which results in different ranges of torque, depending on the

rotational speed; and (2) when an operator mounts a different instrument, having a different torque limit, on a handpiece. Neither of these circumstances discloses, or suggests, applicants' claimed torque selection feature providing *operator selection of preselected torque levels* delivered by the drive assembly to the drive shaft *independent of the rotational speed*. Applicants submit that this feature, as specified in amended claim 6, and the flexibility it provides to an operator, is neither taught nor suggested by the prior art or any combination of prior art teachings. Applicants submit that claim 6, and the claims dependent therefrom, are in allowable form.

Claim 18 was rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (U.S. Patent 6,398,755). This rejection is respectfully traversed in view of the following remarks.

Claim 18 specifies that the drive motor, housed in the control pod, is coupled to *an actuator slidably mounted on the catheter system distally to the control pod and in operable communication with the drive system, wherein the actuator incorporates a switch that activates at least one of the drive system and an aspiration system*. One embodiment of this actuator is illustrated in Fig. 3B; placement of the actuator on the catheter system distally of the control pod is illustrated in Fig. 1. The actuator and its operation are described in Applicants' specification, as published, at paragraphs 0064 and 0065.

The Examiner notes that Belef discloses a system wherein the actuator incorporates a switch that activates the drive system and acknowledges that Belef does not teach an actuator mounted on the catheter system distally to the control pod. The Examiner concludes, however, that it would have been obvious to one of ordinary skill in the art to place the actuating switch distally of the control pod, since rearranging parts of an invention involves only routine skill in the art (citing *In re Japikse*, 86 USPQ 70). Applicants disagree with this conclusion.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness, i.e., whether the claimed invention "as a whole" would have been obvious at a time just before the invention was made to a hypothetical person of ordinary skill in the art. The tendency to resort to hindsight after reviewing the applicants' disclosure is often difficult to avoid, but it must be avoided. Additionally, the Examiner must articulate reasoning with a rational underpinning to support the legal conclusion of obviousness.

In *In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950), claims to a hydraulic power press that read on the prior art except with regard to the position of the starting switch were held unpatentable -- *because* shifting the position of the starting switch *would not have modified the operation of the device*. The MPEP notes, with respect to obviousness conclusions based on the rearrangement of parts: "The mere fact that a worker in the art *could* rearrange the parts of the reference device to meet the terms of the claims is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device." *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984.) The U.S. Supreme Court has also observed, relevant to this situation, that the mere fact that references can be combined or modified does not render the resultant combination obvious unless ~~**>~~the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (USSC 2007).

Belef et al. disclose a driveable catheter system in which manual translational movement of the catheter core is accomplished through the use of a pull-back sled that operates on a drive track. The catheter drive unit (22) travels along a drive track (61), producing translation of the catheter core but not of the sheath. This is a relatively complicated system and translation of the catheter core is limited by the length of the drive track.

Applicant's system incorporates an actuator slidably mounted on the catheter system distally to the control pod and in operable communication with the drive system, the actuator incorporating a switch that activates either the drive system or an aspiration system, or both. Applicants' positioning of an actuator distally to the control pod provides many advantages, one of which is to permit an operator to activate either the drive system, or an aspiration system, or both, at the same time that the operator manually advances the catheter system by grasping it at a location distal to the control pod, very near the actuator. This feature may also enable an operator to simultaneously advance the catheter system and actuate the drive system and/or an aspiration system using the same hand, which provides both convenience and flexibility. This feature, furthermore, overcomes the limitation in translation (distance) of the catheter core that results from the limited length of the drive track in Belef et al.

The Examiner's reasoning that rearranging parts of an invention involves only routine skill in the art is a true statement with respect to some parts, some inventions and some rearrangements. Applicants submit, however, applicants' pending claim 18, in which an actuator activating at least one of the drive system and an aspiration system is slidably mounted on the catheter system distally to the control pod and in operable communication with the drive system is *not* an obvious rearrangement of prior art parts as stated by the Examiner.

Applicants submit that claim 18, and the claims dependent therefrom, are in allowable form.

Claim 56 was rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (US 6,398,755) in view of U.S. Patent 5,584,843 to Wulfman et al.. This rejection is respectfully traversed in view of the following remarks.

The teachings of Belef et al. are described above and, as noted by the Examiner, Belef et al. fail to teach a guidewire brake. The Wulfman et al. '843 patent, as well as other references cited by the Examiner, describe a guidewire brake and certain guidewire brake control features. The Examiner refers to Col. 5, line 18 of Wulfman, which describes a mode of operation in which a catheter and a guidewire are advanced as one unit: the drive shaft and operating head(s) are both translated and rotated during this operation, while the guidewire is translated with the drive shaft but does not rotate. The guidewire is clamped as the drive shaft and guidewire are advanced as a unit while the guidewire, requiring the guidewire brake to translate along with the drive shaft (and the advancer controlling translation of the drive shaft). Wulfman disclose rotation of the drive catheter and guidewire independently from one another and at different speeds and contemplates rotation of a guidewire and a guidewire tip at different speeds. Applicants do not perceive, however, that Wulfman disclose guidewire brake operating modes other than conventional clamped and released modes, or that Wulfman disclose or suggest a guidewire brake control system interrupt or selectable interrupt override control as specified in applicants' claim 56.

Claim 56 specifies that the catheter assembly additionally comprises, *inter alia*, a guidewire brake operable to clamp a guidewire in a stationary position when engaged and to allow translation of the guidewire through the brake when released; a guidewire brake interrupt that prevents the drive system from being actuated when the guidewire brake is in a release

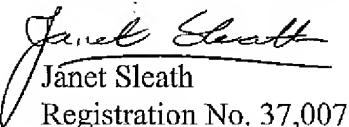
position, and a selectable guidewire brake interrupt override control that, when actuated, provides a guidewire brake operating mode that permits an operator to translate and/or rotate the drive shaft and operating head at low speed while the guidewire is simultaneously moved. Applicants do not perceive that this feature is disclosed in, or suggested by any of the prior art references cited by the Examiner and furthermore submit that this feature is not obvious in view of any combination of features, or teachings, of the prior art references relied upon for rejection. Applicants submit that claim 56, and the claims dependent therefrom, are in allowable form.

Claims 2, 3, 4, 5, 9, 10, 16, 17, 19, 24, 27, 28, 29, 32 and 58-65 were rejected under 35 U.S.C. §103(a) as being unpatentable over Belef et al. (US 6,398,755) in view of U.S. Patent 5,921,956 to Grinberg et al., U.S. 2002/0007190 to Wulfman et al., U.S. Patent 6,565,588 to Clement et al., U.S. Patent 5,584,843 to Wulfman et al, and U.S. Patent 5,540,681 to Strul et al. Applicants believe that the pending independent claims are allowable in view of the prior art rejections stated above and submit that the dependent claims are therefore allowable as well.

Conclusion

In view of the above amendments and remarks, applicants believe that the pending claims 2-7, 9, 10, 16-19, 24, 27-29, 32, 56 and 58-65 are now in condition for allowance. Early consideration and allowance of all the pending claims are respectfully requested. The Examiner is invited to contact Ann W. Speckman at 206-382-1191 if discussion of Applicants' pending claims, or the teachings of the prior art relied upon for rejection, would advance prosecution of Applicants' claims.

Respectfully submitted,


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